

BEST AVAILABLE COPY

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-32 (canceled)

Claim 33. (currently amended) A method of increasing localized bloodflow in tissues to increase growth rate and repair of cells by delivering a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives, to skin comprising the step of:

applying topically to the skin a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance [[of]] to increase localized tissue bloodflow when combined with a concentration of an agent sufficient to create a hostile biophysical environment which causes the substance to migrate from the delivery vehicle to the skin where the substance is absorbed by tissue causing increased rate of repair of cells in the area surrounding the skin wherein the substance was applied.

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 34. (currently amended) The method of claim 33 wherein the delivery vehicle selected from the group consisting of topical creams, topical liquids, topical lotions and topical ointments containing the substance and the ionic salt is a mixture [[consisting of]] comprising sodium chloride (0.25% to 25%), choline chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%) is applied to the skin.

Claim 35. (currently amended) The method of claim 33 wherein a hydrophobic delivery vehicle containing the substance and the ionic salt is a mixture [[consisting of]] comprising sodium chloride (0.25% to 25%), choline chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%) applied to the skin.

Claims 36-37 (canceled)

Claim 38. (previously presented) The method of claim 33 wherein a transdermal patch containing the substance and a penetrating agent is applied to the skin.

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 39. (currently amended) A method of delivering a nitric oxide releasing substance selected from [[a member of]] the group consisting of L-arginine, L-arginine salts and L-arginine derivatives, to skin comprising the step of [[topically]]:

applying topically to the skin a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance, and a concentration of ionic salt sufficient to create a hostile biophysical environment which causes the substance to migrate from the delivery vehicle to the skin where the substance is absorbed by tissue wherein said delivery vehicle comprises water (20-80%), mineral oil (3-18%), glyceryl stearate (0.5-12%), squalene (0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate (0.1-11%), wheat germ oil (0.1-6%), glyceryl stearate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol (0.05-5%), tocopherol acetate (0.05-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

(0.25% to 25%), and magnesium chloride (0.25% to 25%) is applied to the skin.

Claim 40. (previously presented) The method of claim 39 wherein a delivery vehicle also including choline chloride (0.25-25%) is applied to the skin.

Claim 41. (previously presented) The method of claim 39 wherein a delivery vehicle containing L-arginine glutamate (0.25-25%) is applied to the skin.

Claim 42. (previously presented) A method of treating impotence in a male comprising:

delivering a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives to the penis by topically applying to the penis a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance to increase penis bloodflow when combined with a concentration of an agent sufficient to create a hostile biophysical environment which causes the substance to migrate from the vehicle to the penis where the substance is absorbed by tissue.

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 43. (currently amended) The method of claim 42 wherein the delivery vehicle selected from [[a member of]] the group consisting of topical creams, topical liquids, topical lotions and topical ointments containing the substance is L-arginine hydrochloride .25% to 25% by weight and the ionic salt is choline chloride at 10% by weight, sodium chloride at 10% by weight and magnesium chloride at 5% by weight.

Claim 44. (previously presented) The method of claim 42 wherein a hydrophobic delivery vehicle containing the substance wherein the substance is L-arginine hydrochloride at 12.5% by weight and the ionic salt is choline chloride at 10% by weight, sodium chloride at 10% by weight and magnesium chloride at 5% by weight is applied to the penis.

Claims 45-46 (canceled)

Claim 47. (currently amended) A method of treating impotence in a male comprising:

delivering a nitric oxide releasing substance selected from [[a member of]] the group consisting of L-

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

arginine, L-arginine salts and L-arginine derivatives, to skin; [[comprising the step of topically]]

applying topically to the penis a delivery vehicle for the substance, said delivery vehicle containing an effective amount of substance, and a concentration of ionic salt sufficient to create a hostile biophysical environment which causes the substance to migrate from the vehicle to the penis where the substance is absorbed by tissue wherein said delivery vehicle comprises wherein said delivery vehicle comprises water (20-80%), mineral oil (3-18%), glyceryl stearate(0.5-12%), squalene(0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate (0.1-11%), wheat germ oil (0.1-6%), glyceryl stearate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol(0.05-5%), tocopherol acetate (0.05-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%) is applied to the penis.

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 48. (previously presented) The method of claim 47 wherein the delivery vehicle further comprising choline chloride (0.25-25%) is applied to the penis.

Claim 49. (previously presented) The method of claim 47 wherein the delivery vehicle further containing L-arginine glutamate (0.25-25%) is applied to the penis.

Claim 50. (previously presented) The method according to any of the preceding claims wherein the delivery vehicle is contained in a condom which is placed on the penis.

Claim 51. (currently amended) A method of promoting hair growth comprising:

delivering a substance that is a nitric oxide precursor selected from a group consisting of L-arginine and L-arginine derivatives [[, wherein]] to a selected area of the skin where hair growth is desired by topically applying to the selected area of skin where hair growth is desired a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance to increase localized tissue bloodflow when combined with a concentration of an agent sufficient to create a hostile biophysical environment which causes the substance to

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

migrate from the vehicle to the selected area of skin where the substance is absorbed by tissue causing hair growth.

Claim 52. (currently amended) The method of claim 51 wherein the delivery vehicle is selected from the group consisting of topical creams, topical liquids, topical lotions and topical ointments and is applied to the selected area of skin where hair growth is desired wherein the ionic salt is a mixture [[consisting of]] comprising sodium chloride (0.25% to 25%), choline chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%) and mixtures thereof.

Claim 53. (previously presented) The method of claim 51 wherein a hydrophobic delivery vehicle containing the substance, a penetrating agent, and the ionic salt is applied to the selected area of skin where hair growth is desired.

Claims 54-55 (canceled)

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 56. (currently amended) A method of promoting hair growth comprising:

delivering a nitric oxide releasing substance selected from [[a member of]] the group consisting of L-arginine, L-arginine salts and L-arginine derivatives, to a selected area of the skin where hair growth is desired by topically applying to the selected area of skin where hair growth is desired by a delivery vehicle for the substance, and a concentration of ionic salt sufficient to create a hostile biophysical environment which causes the substance to migrate from the delivery vehicle to the skin where the substance is absorbed by tissue wherein said delivery vehicle comprises water (20-80%), mineral oil (3-18%), glyceryl stearate (0.5-12%), squalene (0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate (0.1-11%), wheat germ oil (0.1-6%), glyceryl stearate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol (0.05-5%), tocopherol acetate (0.05-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), L-arginine hydrochloride (0.25%

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

to 25%), sodium chloride (0.25% to 25%), and magnesium chloride (0.25% to 25%) is applied to the selected area of skin where hair growth is desired.

Claim 57. (previously presented) The method of claim 56 wherein a delivery vehicle comprising choline chloride (0.25-25%) is applied to the selected area of skin where hair growth is desired.

Claim 58. (previously presented) The method of claim 56 wherein a delivery vehicle also comprising L-arginine glutamate (0.25-25%) is applied to the selected area of skin where hair growth is desired.

Claim 59. (currently amended) The method of claim 51 wherein a transdermal patch containing the delivery vehicle, wherein the substance in the delivery vehicle is selected from [[a]] the group consisting of L-arginine glutamate (0.25% to 25%), L-arginine hydrochloride (0.25% to 25%) and mixtures thereof is applied to the skin where hair growth is desired.

Claim 60 (canceled)

Appl. No. 08/932,227
Amtd Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 61. (currently amended) A method of delivering a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives, to skin comprising the step of:

topically applying to the skin a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance of 0.25 % to 25% by weight within a packaging selected from the group consisting of a liposome, emulsion of collagen, or collagen peptides said packaging being at a concentration sufficient to create an hostile biophysical environment which causes the liposome to migrate from the delivery vehicle to the skin where the substance is released from the packaging and absorbed by tissue.

Claim 62. (previously presented) The method of claim 61 wherein the delivery vehicle for the substance is applied to the penis so that the packaging migrate from the delivery vehicle to the penis where the substance is released from the packaging and absorbed by tissue.

Appl. No. 08/932,227
Amtd. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 63. (previously presented) The method of claim 61 wherein the delivery vehicle for the substance is applied to the selected area of skin where hair growth is desired so that the liposomes migrate from the delivery vehicle to the skin where the substance is released from the liposome and absorbed by tissue.

Claim 64. (currently amended) A method of topically treating a medical condition comprising the steps of:

selecting a condition from the group consisting of baldness, poor localized blood flow, leg ulcers, superficial ulcers, bedsores [[wounds, sexual dysfunction]] and erectile dysfunction;

selecting a nitric oxide precursor means;

selecting a means of delivering the substance to the skin; and,

applying topically to the skin having the selected condition, an effective amount of the nitric oxide precursor means, the nitric oxide precursor means being 0.25 % to 25% by weight of the means of delivering the substance to the skin.

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 65. (previously presented) The method of topically treating a medical condition of claim 64 further comprising the step of:

selecting a means of producing a hostile biophysical environment which increases the migration of the nitric oxide precursor means into the skin.

Claim 66. (previously presented) The method of topically treating a medical condition of claim 65 wherein the means of producing a hostile biophysical environment is an ionic salt having a concentration of 0.25 to 25% of the means of delivering the substance to the skin.

Claim 67. (previously presented) The method of topically treating a medical condition of claim 66 wherein the nitric oxide precursor means is selected from the group consisting of D,L-arginine, L-arginine, alkyls of L-arginine, esters of L-arginine, and salts of L-arginine.

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 68. (previously presented) The method of topically treating a medical condition of claim 67 wherein the alkyls of L-arginine are selected from the group consisting of ethyl, methyl, propyl, isopropyl, butyl, isobutyl, and t-butyl.

Claim 69. (previously presented) The method of topically treating a medical condition of claim 67 wherein the salts of L-arginine are selected from the group consisting of hydrochloride, glutamate, butyrate, and glycolate.

Claim 70. (previously presented) The method of increasing localized blood flow in tissues to increase growth and repair of cells of claim 33 wherein an effective amount of the substance is 0.25 to 25% by weight of the delivery vehicle.

Claim 71. (previously presented) The method of increasing localized bloodflow in tissues to increase growth and repair of cells of claim 33 wherein the agent is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, L-arginine chloride, L-arginine

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

gluamate, L-arginine butyrate, L-arginine glutamate and mixtures thereof.

Claim 72. (previously presented) The method of increasing localized bloodflow in tissues to increase growth and repair of cells of claim 71 wherein the agent has a concentration of 0.25 to 25% by volume of the delivery vehicle.

Claim 73. (previously presented) The method of increasing localized bloodflow in tissues to increase growth and repair of cells of claim 33 wherein the agent is selected from a group consisting of a high ionic strength environment, neutralization of L-arginine's charge in a complex, inclusion in a liposome, high pH, low pH, pharmaceutically acceptable acids, pharmaceutically acceptable bases, highly hydrophobic environments, polylysine, polyglutamine, polyaspartate, copolymers of charged amino acids, oleoresin, and capsicum.

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 74. (previously presented) The method of treating impotence of claim 42 wherein an effective amount of the substance is 0.25 to 25% by weight of the delivery vehicle.

Claim 75. (previously presented) The method of treating impotence of claim 42 wherein the agent is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, L-arginine chloride, L-arginine gluamate, L-arginine butyrate, L-arginine glutamate and mixtures thereof.

Claim 76. (previously presented) The method of treating impotence of claim 75 wherein the agent has a concentration of 0.25 to 25% by volume of the delivery vehicle.

Claim 77. (previously presented) The method of treating impotence of claim 42 wherein the agent is selected from a group consisting of a high ionic strength environment, neutralization of L-arginine's charge in a complex, inclusion in a liposome, high pH, low pH, pharmaceutically acceptable acids, pharmaceutically acceptable bases, highly

Appl. No. 08/932,227
Amdt. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

hydrophobic environments, polylysine, polyglutamine, polyaspartate, copolymers of charged amino acids, oleoresin, and capsicum.

Claim 78. (previously presented) The method of promoting hair growth of claim 51 wherein an effective amount of the substance is 0.25 to 25% by weight of the delivery vehicle.

Claim 79. (previously presented) The method of promoting hair growth of claim 51 wherein the agent is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, L-arginine chloride, L-arginine gluamate, L-arginine butyrate, L-arginine glutamate and mixtures thereof.

Claim 80. (previously presented) The method of promoting hair growth of claim 79 wherein the agent has a concentration of 0.25 to 25% by volume of the delivery vehicle.

Appl. No. 08/932,227
Amtd. Dated Sep. 29, 2004
Reply to Notice of Jul. 29, 2004

Claim 81. (previously presented) The method promoting hair growth of claim 51 wherein the agent is selected from a group consisting of a high ionic strength environment, neutralization of L-arginine's charge in a complex, inclusion in a liposome, high pH, low pH, pharmaceutically acceptable acids, pharmaceutically acceptable bases, highly hydrophobic environments, polylysine, polyglutamine, polyaspartate, copolymers of charged amino acids, oleoresin, and capsicum.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.